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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-----------------------------------|------------------------|
| 10/519,983 | 01/04/2005 | Yasuhiro Kajihara | TAM-051 | 3218 |
| 20374 7590 06/07/2007 KUBOVCIK & KUBOVCIK SUITE 710 900 17TH STREET NW WASHINGTON, DC 20006 | | | EXAMINER HEARD, THOMAS SWEENEY | |
| | | | ART UNIT 1654 | PAPER NUMBER |
| | | | MAIL DATE 06/07/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/519,983

Applicant(s)

KAJIHARA, YASUHIRO

Examiner

Thomas S. Heard

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 15 and 17-21 is/are pending in the application.
- 4a) Of the above claim(s) 15 and 17-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 01/04/2005.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 15, 17-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/28/2007. Applicants have elected Group I, Claims 1-12. Applicants have further complied with the election of species requirement. Applicants have elected:

- (A) Glycopeptide having at least six sugar residues;
- (B) (a) Fmoc group as the fat-soluble protective group and (b) benzyl group as the protective group for the carboxyl group of the sialic acid;
- (D) (1) a combination of HOBt-H₂O and DIPCDI as a reagent to amidate; (2) piperidine as a reagent to remove protecting groups; and (3) DCC as a reagent to esterify the hydroxyl group.

Claims 1-12, 15, 17-21 are pending. Claims 1-12 are hereby examined on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al, US Pub No. 2003/0229013 and Toshiyuki et al, Japanese Patent Application No: 10-082882, Applicant's IDS.

The instantly claimed invention is drawn to a process of synthesizing a glycosylated peptide through the use of Solid Phase Chemical Synthesis employing Fmoc protected amino acids and with an Asp amino acid that is coupled to a sugar.

Wu, et al discloses solid phase chemical synthesis employing the common coupling reagents DCC, HOBt-H₂O, and DIPCDI and resins, such as Wang resin, where the peptide is linked at the C-terminal (Carboxyl) end, see paragraphs [0023] through [0042] for reagents and resins. The synthesis is by coupling the peptide to a resin (Wang) and followed by deprotecting the Fmoc-protected amino-terminus of the peptide and coupling a new Fmoc protected amino protected amino acid to the growing peptide chain. The Fmoc protective reagent used for protecting the amino acids is fat soluble. Wu, et al, does not teach the coupling of an Fmoc protected amino acid that has a sugar residue covalently coupled to the amino acid.

Toshiyuki teaches an Fmoc protected sugar-linked asparagine that is coupled to Fmoc and is used to incorporate a glycosylated amino acid into the synthesis process, see abstract. Toshiyuki et al teaches that the sugar portion of the sugar-linked Asp residues may be a monosaccharide or a sugar chain, readable on having 6 to 9 sugar residues. Toshiyuki et al finally teaches that the hydroxyl residues on the sugar chain may be deprotected, see schemes throughout the entire short application.

The difference between what is instantly claimed and what is taught in the prior art is that the instantly claimed invention incorporates Toshiyuki's Fmoc protected sugar-linked Asp residue. It would have been obvious at the time of the instantly claimed invention to incorporate Fmoc protected sugar-linked Asp residues into the well known Merrifield solid phase peptide synthesis in order to make a glycosylated peptide. One would have been motivated to do so given Toshiyuki's teaching that Fmoc protected sugar-linked Asp residues are compatible with peptide synthesis. One would have had a reasonable expectation of success given Toshiyuki's teaching that sugar-linked Asp residues can be used in peptide synthesis and that the methodology of solid phase synthesis is so well known that one of ordinary skill in the art would be able to adapt the coupling steps beyond Toshiyuki's teaching to incorporate numerous and different sugar residues beyond those instantly claimed. Given the teaching of the references, therefore, it would have been prima facie obvious at the time of the invention to combine the teaching of Wu and Toshiyuki to arrive at the instantly claimed invention.

Conclusion

No Claims are allowed.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas S. Heard whose telephone number is (571) 272-2064. The examiner can normally be reached on 9:00 a.m. to 6:30 p.m..


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TSH



 6/14/07
ANISH GUPTA
PRIMARY EXAMINER